



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2008-N-0500]

Agency Information Collection Activities; Proposed Collection; Comment Request;

Requirements on Content and Format of Labeling for Human Prescription Drug and

Biological Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the Federal Register concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection provisions of FDA's requirements on content and format of labeling for human prescription drug and biological products.

DATES: Submit either electronic or written comments on the collection of information by

[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit electronic comments on the collection of information to

<http://www.regulations.gov>. Submit written comments on the collection of information to the

Division of Dockets Management (HFA 305), Food and Drug Administration, 5630 Fishers

Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE-14526, Silver Spring, MD 20993-0002, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the Federal Register concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products (OMB Control Number 0910-0572)--Extension

FDA's regulations governing the format and content of labeling for human prescription drug and biological products were revised in the Federal Register of January 24, 2006 (71 FR 3922), to require that the labeling of new and recently approved products contain highlights of prescribing information, a table of contents for prescribing information, reordering of certain sections, minor content changes, and minimum graphical requirements. These revisions were intended to make it easier for health care practitioners to access, read, and use information in prescription drug labeling; to enhance the safe and effective use of prescription drug products; and to reduce the number of adverse reactions resulting from medication errors due to misunderstood or incorrectly applied drug information.

Currently, § 201.56 (21 CFR 201.56) requires that prescription drug labeling contain certain information in the format specified in either § 201.57 (21 CFR 201.57) or § 201.80 (21 CFR 201.80), depending on when the drug was approved for marketing. Section 201.56(a) sets forth general labeling requirements applicable to all prescription drugs. Section 201.56(b) specifies the categories of new and more recently approved prescription drugs subject to the revised content and format requirements in §§ 201.56(d) and 201.57. Section 201.56(c) sets forth the schedule for implementing these revised content and format requirements. Section 201.56(e) specifies the sections and subsections, required and optional, for the labeling of older prescription drugs not subject to the revised format and content requirements.

Section 201.57(a) requires that prescription drug labeling for new and more recently approved prescription drug products include “Highlights of Prescribing Information”. Highlights provides a concise extract of the most important information required under § 201.57(c) (the Full

Prescribing Information (FPI)), as well as certain additional information important to prescribers. Section 201.57(b) requires a table of contents to prescribing information, entitled “Full Prescribing Information: Contents,” consisting of a list of each heading and subheading along with its identifying number to facilitate health care practitioners' use of labeling information. Section 201.57(c) specifies the contents of the FPI. Section 201.57(d) mandates the minimum specifications for the format of prescription drug labeling and establishes minimum requirements for key graphic elements such as bold type, bullet points, type size, and spacing.

Older drugs not subject to the revised labeling content and format requirements in § 201.57 are subject to labeling requirements at § 201.80. Section 201.80(f)(2) requires that within 1 year, any FDA-approved patient labeling be referenced in the “Precautions” section of the labeling of older products and either accompany or be reprinted immediately following the labeling.

Annual Burden for Prescription Drug Labeling Design, Testing, and Submitting to FDA for New Drug Applications (NDAs) and Biologics License Applications (BLAs) (§§ 201.56 and 201.57). New drug product applicants must: (1) Design and create prescription drug labeling containing “Highlights”, “Contents”, and FPI, (2) test the designed labeling (e.g., to ensure that the designed labeling fits into carton-enclosed products), and (3) submit it to FDA for approval. Based on the projected data used in the January 24, 2006, final rule, FDA estimates that it takes applicants approximately 3,349 hours to design, test, and submit prescription drug labeling to FDA as part of an NDA or a BLA under the revised regulations. Currently, approximately 131 applicants submit approximately 196 new applications (NDAs and BLAs) to FDA annually, totaling 656,404 hours.

FDA estimates the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden¹

21 CFR Part	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Labeling Requirements in §§ 201.56 and 201.57	131	1.5	196	3,349	656,404

¹There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: January 13, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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